Plaintiffs' Memorandum in Opposition to Joint Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims

Ex 51 – HDA_MDL_000156141-260 Excerpts

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

EXECUTIVE COMMITTEE CONFERENCE CALL

April 6, 2012
10:00 AM EDT

Minutes of the
HDMA Executive Committee Conference Call

April 6, 2012
10:00 AM EDT

HDMA Executive Committee Members Present:

David Moody (Chair)	CEO, Mutual Wholesale Drug Company
David Neu (Vice Chairman)	President, AmerisourceBergen Drug Corporation
Ken Couch	President, Smith Drug Company
John M. Gray	President and CEO, HDMA
Paul Julian	Executive Vice President and Group President, McKesson Corp.
Mike Kaufmann	CEO, Pharmaceutical Segment, Cardinal Health, Inc.
Ted Scherr	President and CEO, Dakota Drug
Dale Smith	Chairman and CEO, HD Smith

HDMA and CHSCR Staff:

Perry Fri	Senior Vice President, Industry Relations, Membership & Education

Outside Legal Counsel:

Richard L. Frank, Esq.	Olsson Frank Weeda Terman Matz PC (OFW Law)

PROCEEDINGS

I. **WELCOME AND INTRODUCTION.** President John Gray thanked Executive Committee members for agreeing to participate in a conference call to address recent activity with respect to suspicious order monitoring and the role of healthcare distributors. HDMA has testified before Congress and prepared an *amicus curiae* brief for filing with the federal Court of Appeals in the *Cardinal v. Holder* litigation.

Chairman Moody and Vice Chairman Neu expressed concern about the trend of recent developments and thought it time for the Executive Committee to review recent events and plot a course for going forward.

President Gray reviewed recent activities and options for moving forward.

1. Partnership at Drugfree.org (formerly Partnership for a Drug-Free America) (PDFA). HDMA has been invited to participate in a program with the PDFA to study how government and industry can better manage the pharmaceutical supply chain to eliminate controlled substance diversion and abuse. PDFA has submitted

a proposal to HDMA for the first phase of the project. That proposal was shared with Executive Committee members on April 2, 2012.

Action: On motion duly made and seconded, $200,000 was allocated from reserves to fund Phase I of the PDFA project.

2. HDMA is sponsoring the National Governors Association Prescription Drug Abuse Reduction Policy Academy. This is a special project that NGA is undertaking to address the growing incidence of prescription drug abuse in the United States. HDMA contributed $25,000 to help underwrite this project.

3. HDMA is stepping up its efforts to educate the public, through the media, about the controlled substance supply chain and efforts being undertaken by distributors to prevent diversion and reduce prescription drug abuse.

4. President Gray reported that HDMA, along with outside counsel (OFW Law), plan to meet with Rich Cooper, Esq. and Bob Bennett, Esq. of Williams & Connolly to discuss other potential means of engaging DEA to better understand and manage suspicious ordering monitoring efforts.

5. HDMA is coordinating its efforts with NACDS.

There being no further, the conference call adjourned.

Prepared by:

Richard L. Frank

Richard L. Frank, Counsel
Dated: May 8, 2012

Approved by:

Ann W. Bittman

Ann W. Bittman, HDMA Secretary
Dated: May 8, 2012

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

EXECUTIVE COMMITTEE MEETING

JW Marriott San Antonio Hill Country
San Antonio, Texas

June 10, 2012

Minutes of the
HDMA Executive Committee Meeting

JW Marriott San Antonio Hill Country
San Antonio, Texas

June 10, 2012

ATTENDANCE:

HDMA Executive Committee Members Present:

David Moody (Chair)	CEO, Mutual Wholesale Drug Company
David Neu (Vice Chair)	Senior Vice President and President, AmerisourceBergen Drug Corporation
Ken Couch	President, Smith Drug Company
John Gray	President & CEO, HDMA
Mike Kaufmann	CEO, Pharmaceutical Segment, Cardinal Health, Inc.
Ted Scherr	President & CEO, Dakota Drug, Inc.
Dale Smith	Chairman and CEO, HD Smith *(via conference call)*

HDMA Executive Committee Members Absent:

Paul Julian	Executive Vice President & Group President, McKesson Corp.

HDMA Staff Present:

Ann Bittman	HDMA Executive Vice President & COO
Anita Ducca	HDMA Vice President, Regulatory Affairs
Perry Fri, Sr.	HDMA Vice President, Industry Relations, Membership & Education
Elizabeth Gallenagh	HDMA Vice President, Government Affairs and General Counsel *(via conference call)*
Patrick Kelly, Sr.	HDMA Vice President, Government Affairs
Brooke Naylor	HDMA Vice President, Meetings & Conferences
John Parker	HDMA Vice President, Communications
Ted Pezzullo	HDMA Vice President, Information Technology and Facilities
Karen Ribler	Executive Vice President & COO, Center for Healthcare Supply Chain Research

Legal Counsel

Richard L. Frank, Esq.	Olsson Frank Weeda Terman Matz PC

PROCEEDINGS

I. **WELCOME AND INTRODUCTION.** President John Gray thanked Executive Committee members for participating in the Business & Leadership Conference. He noted an excellent attendance is expected for the conference and a productive agenda.

A. Chairman Dave Moody (Mutual Wholesale Drug Company) welcomed the Executive Committee and noted that the morning's focus would be on pedigree and DEA matters; the Board meeting in the afternoon will cover a broader range of topics.

B. **Approval of Prior Meetings Minutes (Executive Committee Materials, Pages 7-15).**

Richard L. Frank (OFW Law), HDMA Outside Counsel, drew the Executive Committee's attention to minutes of the February 16, 2012 Executive Committee meeting at Pebble Beach, California and the April 6, 2012 Executive Committee conference call.

Action: On motion duly made and seconded, the minutes of the February 16, 2012 Executive Committee meeting were approved.

Action: On motion duly made and seconded, the minutes of the April 6, 2012 Executive Committee conference call were approved.

C. **Antitrust Policy Review (Executive Committee Materials, Page 4).**

Mr. Frank drew the Executive Committee's attention to the HDMA Antitrust Policy. He reminded the Executive Committee of HDMA's unqualified policy of strict compliance with the antitrust laws and noted that the agenda and background materials had been reviewed and approved in advance. Mr. Frank advised that meeting proceedings would be closely monitored and interrupted if and when topics or discussions created even the appearance of antitrust noncompliance.

D. **Legal Issues Report.**

Mr. Frank presented a short legal issues update.

- FDA Grand Jury in Puerto Rico – Distributor Investigation – no further activity since February 16, 2012 meeting. HDMA is still awaiting dates from OCI Investigator and Assistant U.S. Attorney for interview. HDMA is not a target of the investigation.

- Qui Tam Litigation – Motions to Dismiss and a brief in opposition were filed in February 2012. Oral argument was held on May 18, 2012. The Judge's decision on the Motion to Dismiss could come at any time.

- *Cardinal Health v. Holder (DEA)* – HDMA filed an *amicus curiae* brief in support of Cardinal Health's position before the Federal Court of Appeals for the District of Colombia Circuit. Cardinal subsequently reached a settlement with DEA and withdrew its appeal. The DEA administrative proceeding was terminated; Cardinal Health agreed to a two-year suspension of its Lakeland facility registration and some enhanced regulatory oversight by DEA.

- Project Paperless – President Gray informed the Executive Committee that HDMA settled the case for $32,500 and now has a license to continue its copy-scan-to-computer activities.

II. FINANCIAL/GOVERNANCE MATTERS (Executive Committee Materials, Tab A).

A. Financial Update.

Ms. Ann Bittman (HDMA Executive Vice President & COO) presented the financial update through April 30, 2012. Ms. Bittman reported the Association's financial condition is strong and that they are projecting operating results for 2012 at slightly better than budget. Projected year-end net surplus is slightly above $280,000. If the carry-over surplus from 2011 of $107,500 is included, the Association is projecting an operating surplus of $389,000 for 2012. This figure assumes that the Business & Leadership Conference will meet its net income target. Currently, income is approximately $112,000 shy of budget, meaning the projected year-end surplus could be correspondingly reduced.

On the revenue side, through April 30, 2012, collections are $637,000 ahead of budgeted revenue due to higher manufacturer dues, increased sponsorship revenue, improved results from the Distribution Management Conference (DMC), utilization of the SBDA reserve fund ($183,500), and new sponsorship revenue of $26,000 from the HBW research project.

On the expense side, through April 30, 2012, expenses were $356,000 over budget due, in large part, to the planned addition of the 4% discretionary 401(k) contribution, increased professional fees, and slightly higher expenses from the DMC.

As of April 30, 2012, the reserve fund balance is $12.17 million, which meets the target of maintaining one year's operating expenses.

B. Center for Healthcare Supply Chain Research Board of Directors (Executive Committee Materials, Tab A, pages 28-30).

Ms. Karen Ribler (Executive Vice President & COO, Center for Healthcare Supply Chain Research) presented the proposed slate of officers and Board members for the Center which requires approval by the HDMA Executive Committee.

Vice Chairman (completing Hal Korman's term that ends December 2012) – Jeff Watson, President, Apotex Corporation

Board Member – Robert Potter, Executive Vice President, Sales and Channel Development, Mylan Inc.

Board Member – Rebecca Lyons, Esq., Vice President, Strategy and Supply Chain Services, Johnson & Johnson Health Care Systems

Action: On motion duly made and seconded, the slate of officers and Board members was unanimously approved.

III. UPDATE ON STRATEGIC PLANNING PROCESS.

Mr. Perry Fri (HDMA Vice President, Industry Relations, Membership & Education) presented a brief update on the strategic planning process from the February 2012 meeting. The financial situation has improved providing more time to consider and implement structural changes. The ability to carry over surpluses into the next year's operating budget, as approved by the Executive Committee in February, has helped ($107,500 from 2011). Outside Counsel has indicated that a By-Laws change is not required to include medical/surgical distributors as members. Mr. Fri has reached out to PSS and Owens & Minor to gauge their interest. Efforts continue to explore growth internationally both with membership and meetings. Mr. Gray is exploring opportunities with IFPW. The Executive Committee encouraged him to discuss the issue with Mark Parrish to see if some form of greater collaboration is possible. HDMA/HIDA dual members on the HDMA Executive Committee (McKesson, Cardinal) will let Mr. Gray know if there is support within their companies for pursuing greater collaboration between HDMA and HIDA, but the consensus was that it is not likely at this time. Finally, HDMA management will review the BLC registration fee structure and determine whether any revision to the fees is warranted for 2013.

IV. DISCUSSION ISSUES (Executive Committee Materials, Tab C, pages 48-56).

A. Pedigree.

Mr. Patrick Kelly (HDMA Vice President, Government Affairs) and Ms. Liz Gallenagh (HDMA Vice President, Government Affairs and General Counsel) provided an update on federal pedigree matters. Senators Bennet (D-CO) and Burr (R-NC) have offered the PDSA (healthcare industry consortium) amendment. Stakeholders, including House and Senate staff, FDA, the Pew Charitable Trust, PDSA, and others, are participating in the debate. Senate staff has set a goal of June 18, 2012 to address and resolve all concerns with the hope of including the amendment in the PDUFA extension legislation. The Bennet/Burr amendment includes a traceability model (not track and trace) by lot number. FDA continues to support traceability to the unit level. The California law begins to take effect in 2015 for manufacturers.

B. **Prescription Drug Abuse, Diversion and DEA.**

Executive Committee members expressed satisfaction with HDMA's role in supporting industry efforts to gain greater clarity from DEA as to what is needed to comply with suspicious order monitoring requirements. Mr. Mike Kaufmann (Pharmaceutical Segment, Cardinal Health, Inc.) thanked Executive Committee members and HDMA for its support during its litigation with DEA. Mr. Kaufmann summarized an NACDS initiative which would rely substantially on SureScripts to electronically capture all controlled substance prescriptions and orders. NACDS is considering support for legislation which would require that all such prescriptions and orders flow through SureScripts or something similar. Challenges include opposition from the American Medical Association and the 27 states which currently do not permit electronic prescriptions.

Mr. Kelly reported that controlled substance related matters that have played a prominent role in the PDUFA process include Senator Manchin's (D-WV) language to reschedule hydrocodone combination products from Schedule III to Schedule II. HDMA is opposing the amendment. HDMA is looking for carve-out language for wholesalers should the Manchin amendment pass. Additional Congressional activity includes Representative Bono Mack's (R-CA) letter to the Secretary of the US Department of Health and Human Services and the US Attorney General seeking clear guidance from DEA on prescription drug diversion issues. Senators Grassley (R-IA) and Whitehouse's (D-RI) requested GAO report on DEA policies and their potential impact on drug shortages. Finally, Senators Baucus (D-MT) and Grassley sent a letter to opioid manufacturers requesting information about financial contributions to entities supporting greater access to pain medicines.
President Gray reported that the $200,000 previously approved by the Executive Committee to work with the Partnership for a Drug Free America likely will be applied instead to other DEA related activities and he will keep them posted.

There being no further, the conference call adjourned.

Prepared by:

Richard L. Frank, Counsel
Dated: June 21, 2012

Approved by:

Ann W. Bittman, HDMA Secretary
Dated: June 21, 2012

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

EXECUTIVE COMMITTEE MEETING

The Ritz Carlton Palm Beach
Manalapan, Florida

September 30, 2012

Minutes of the
HDMA Executive Committee Meeting

The Ritz Carlton Palm Beach
Manalapan, Florida
September 30, 2012

ATTENDANCE:

HDMA Executive Committee Members Present:

David Moody (Chair)	CEO, Mutual Wholesale Drug Company (*via conference call*)
David Neu (Vice Chair)	President, AmerisourceBergen Drug Corporation
Ken Couch	President, Smith Drug Company
John Gray	President & CEO, HDMA
Mike Kaufmann	CEO, Pharmaceutical Segment, Cardinal Health, Inc.
Ted Scherr	President & CEO, Dakota Drug, Inc.
Dale Smith	Chairman and CEO, HD Smith

HDMA Executive Committee Members Absent:

Paul Julian	Executive Vice President & Group President, McKesson Corp.

HDMA Staff Present:

Ann Bittman	HDMA Executive Vice President & COO
Anita Ducca	HDMA Vice President, Regulatory Affairs
Perry Fri	HDMA Senior Vice President, Industry Relations, Membership & Education
Elizabeth Gallenagh	HDMA Vice President, Government Affairs and General Counsel
Patrick Kelly	HDMA Senior Vice President, Government Affairs
Brooke Naylor	HDMA Vice President, Meetings & Conferences
John Parker	HDMA Vice President, Communications
Ted Pezzullo	HDMA Vice President, Information Technology and Facilities
Karen Ribler	Executive Vice President & COO, Center for Healthcare Supply Chain Research

Legal Counsel Present:

Richard L. Frank, Esq.	Olsson Frank Weeda Terman Matz PC

Guest Present:

George Koch, Esq.	K&L Gates

PROCEEDINGS

I. **WELCOME AND INTRODUCTION.** President John Gray thanked Executive Committee members for attending the Annual Board and Membership Meeting. He noted an excellent attendance is expected for the conference and a productive agenda.

A. Chairman Dave Moody (Mutual Wholesale Drug Company) welcomed the Executive Committee by conference call and sent his regrets that for medical reasons he would be unable to attend in person. He thanked Vice Chairman David Neu (AmerisourceBergen Drug Corp.) for chairing the meeting. Vice Chairman Neu thanked the Executive Committee for their attendance and participation.

B. **Antitrust Policy Review (Executive Committee Materials, Page 4).**

Richard L. Frank (OFW Law), HDMA Outside Counsel, drew the Executive Committee's attention to the HDMA Antitrust Policy. He reminded the Executive Committee of HDMA's unqualified policy of strict compliance with the antitrust laws and noted that the agenda and background materials had been reviewed and approved in advance. Mr. Frank advised that meeting proceedings would be closely monitored and interrupted if and when topics or discussions created even the appearance of antitrust noncompliance.

C. **Approval of Prior Meetings Minutes (Executive Committee Materials, Pages 6-11).**

Mr. Frank drew the Executive Committee's attention to minutes of the June 10, 2012 Executive Committee meeting at the J.W. Marriott San Antonio Hill Country Hotel in San Antonio, Texas.

Action: On motion duly made and seconded, the minutes of the June 10, 2012 Executive Committee meeting were approved.

D. **Legal Issues Report.**

Mr. Frank presented the legal issues update.

1. West Virginia Lawsuit (June 2012) – West Virginia Attorney General Darrell McGraw filed suit against 14 out-of-state drug distributors alleging violations of the State Controlled Substances Act and Consumer Credit and Protection Act for their roles in allegedly supplying controlled substances to state "pill mills." AG McGraw seeks to enjoin the distributors from distributing any controlled substances for non-medical purposes, recover damages, establish medical monitoring for drug abuse victims, and mandate reporting suspicious orders to state authorities.

2. DEA Actions in Florida

(a) CVS Caremark – on February 4, 2012, the DEA served an immediate suspension order (ISO) on two CVS pharmacies in Sanford, Florida alleging that the pharmacies were distributing controlled substances in violation of federal law. The matter went before the DEA Administrative Law Judge who issued a recommendation on June 8, 2012 to revoke the pharmacies' DEA registrations. On August 31, 2012, DEA Administrator Michelle M. Leonhart accepted the ALJ's recommendations and issued the final Order to revoke both registrations. CVS may choose to challenge the revocations before the U.S. Court of Appeals for the District of Columbia Circuit.

(b) Walgreens – on September 14, 2012, DEA announced that it had issued an ISO to a Walgreens distribution facility in Jupiter, Florida.

(c) Arizona suit against McKesson – the State of Arizona sued McKesson in Arizona state court alleging violations of the State Consumer Fraud Law. The State alleges that McKesson provided false and misleading average wholesale prices to First DataBank and Medi-Span thereby causing false and inflated prices for the retail sale of certain drugs.

3. *Qui Tam* Litigation (Streck) – on July 3, 2012, the District Court dismissed all counts against the "service fee" defendants and most of the counts against the "discount" defendants. The Court did permit the case to proceed against the "discount" defendants for conduct from January 1, 2007 to October 28, 2008, the date Streck filed the Complaint. Streck has moved to amend the judgment dismissing the "service fee" defendants; that motion is still pending.

4. Grand Jury Subpoena in Puerto Rico Distributor Investigation – no change in status.

II. FINANCIAL/GOVERNANCE MATTERS (Executive Committee Materials, Tab A).

A. Nomination of 2013 Board Officers.

Action: On motion duly made and seconded, the Executive Committee unanimously nominated the following slate of officers for a one-year term (Executive Committee Materials, Tab A, page 13). This slate will be submitted to the full membership on October 1, 2012.

1. David Neu, President, AmerisourceBergen Drug Company for a one-year term as HDMA Chairman

2. Ted Scherr, President and CEO, Dakota Drug, for a one-year term as HDMA Vice Chairman

B. August 2012 Financial Statements.

1. Ms. Ann Bittman (HDMA Executive Vice President & COO) presented the financial update through August 2012 (Executive Committee Materials, Tab A, pages 14-23). Financial reports include the Balance Sheet, Operating Income Statement, Reserve Fund Income Statement, and Consolidated Income Statement. As of August 31, 2012, the Reserve Fund exceeded $12 million. This exceeds HDMA's target of maintaining one year's operating expenses and reserves. Operating revenue was $11.49 million and operating expenses were $7.84 million for a current net surplus of $3.65 million. The projected net surplus for year-end is $350,000 which consists of the current projected net surplus of $242,000 plus the carry-over of $108,000 from the 2011 operating surplus. Overall dues revenue is $262,000 higher than budgeted due to new members and higher manufacturer sales revenue. Projected expenses include the discretionary 401(k) contribution for employees of 4%.

2. Proposed 2013 Budget (Executive Committee Materials, Pages 24-38) – Ms. Bittman presented the proposed 2013 budget including the Operating Budget and Reserve Fund budget. The Operating Budget reflects a deficit of $285,000 which would be more than covered by the projected 2012 operating carryover surplus of $350,000.

   Discussion ensued. Several Executive Committee members expressed the view that a budget balanced without use of the prior year's operating surplus would be preferable. Staff was tasked to prioritize activities and present a balanced budget for Executive Committee consideration by mid-November 2012. In addition, it was agreed that a sponsor should be obtained for the June Board of Directors dinner.

3. Center Board of Directors (Executive Committee Materials, Pages 39-40) – Ms. Karen Ribler (Executive Vice President & COO, Center for Healthcare Supply Chain Research (Center)) presented the proposed slate of officers and directors for the Center.

   Action: On motion duly made and seconded, The Executive Committee approved the Nominating Committee's slate of officers and directors for the Center.

III. STRATEGIC PLANNING PROCESS – UPDATE (Executive Committee Materials, Tab B).

President John Gray and Mr. Perry Fri (HDMA Senior Vice President, Industry Relations, Membership & Education) presented a brief update of action items from the strategic planning process:

- Discussions continue with IFPW and its President, Mark Parrish, to conduct joint activities and possible integration of meetings and conferences.
- No real interest has been expressed in pursuing a merger with HIDA but there is still the possibility of developing a separate HDMA dues category for medical-

surgical distributors. That allows them to pay based on their pharmaceutical sales rather than total company sales.

- A modest decrease in BLC registration fees for small manufacturers is under consideration.
- Exploration of a broadening of the membership categories to include self-distributing chains was discussed briefly and put on hold.
- John Gray explained that Express Scripts is still exploring options for a new organization. It was agreed that HDMA should remain involved in these discussions.

IV. DISCUSSION ISSUES (Executive Committee Materials, Tab C).

A. Rx Drug Abuse and Diversion.

Mr. Patrick Kelly (HDMA Senior Vice President, Government Affairs) updated the Executive Committee. A Controlled Substance Abuse Task Force has been empaneled which is looking at federal, state and public relations issues. The GPPC and RAC recommend focusing first on public relations issues.

Mr. John Parker (HDMA Vice President, Communications) presented an update on the current state of play regarding how wholesalers are being portrayed in the media and their implications for HDMA members. The GPPC has recommended a strategy of education, advocacy and collaboration. The goal is to find a public relations firm to help execute the strategy. Proposals from APCO and GMMB will be made to the Board on October 1, 2012. Discussion ensued regarding the scope of a PR program and the possibility of handling some of this work with staff and member assets. No decisions or recommendations were made. PR firm proposals will be considered by the full Board and the Executive Committee and staff will put together a plan including HDMA staff, member, and third-party assets.

There being no further business, the meeting adjourned.

Prepared by:

Richard L. Frank, Counsel
Dated: October 22, 2012

Approved by:

Ann W. Bittman, HDMA Secretary
Dated: October 22, 2012

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

EXECUTIVE COMMITTEE MEETING

The Four Seasons Hotel
Washington, D.C.

February 22, 2013

Minutes of the
HDMA Executive Committee Meeting

The Four Seasons Hotel
Washington, D.C.

February 22, 2013

ATTENDANCE:

HDMA Executive Committee Members Present:

David Neu (Chair)	President, AmerisourceBergen Drug Corporation
Ken Couch	President, Smith Drug Company
John Gray	President & CEO, HDMA
David Moody	CEO, Mutual Wholesale Drug Company
Dale Smith	Chairman and CEO, HD Smith

HDMA Executive Committee Members Absent:

Paul Julian	Executive Vice President & Group President, McKesson Corp.
Mike Kaufmann	CEO, Pharmaceutical Segment, Cardinal Health, Inc.
Ted Scherr (Vice Chair)	President & CEO, Dakota Drug, Inc.

HDMA Staff Present:

Ann Bittman	HDMA Executive Vice President & COO
Anita Ducca	HDMA Vice President, Regulatory Affairs
Perry Fri	HDMA Senior Vice President, Industry Relations, Membership & Education
Elizabeth Gallenagh	HDMA Vice President, Government Affairs and General Counsel
Patrick Kelly	HDMA Senior Vice President, Government Affairs
Brooke Naylor	HDMA Vice President, Meetings & Conferences
John Parker	HDMA Vice President, Communications
Ted Pezzullo	HDMA Vice President, Information Technology and Facilities
Karen Ribler	Executive Vice President & COO, Center for Healthcare Supply Chain Research

Legal Counsel:

Richard L. Frank, Esq.	Olsson Frank Weeda Terman Matz PC

Guests:

George W. Koch, Esq.	Counsel
Michael Tuffin	Managing Director, Washington, DC, APCO Worldwide
Priscilla VanderVeer	Director, Corporate Communications & Issues Management,

Chrystine Zacherau	APCO Worldwide Director, Health Care Research, APCO Insight, APCO Worldwide

PROCEEDINGS

I. **WELCOME AND INTRODUCTION.** President John Gray thanked the Executive Committee members for attending the meeting and he briefly reviewed the agenda.

A. **Chairman's Remarks.**

Chairman Dave Neu (AmerisourceBergen Drug Corporation) welcomed the Executive Committee and extended the apologies of Paul Julian, Mike Kaufmann, and Ted Scherr, who were unable to attend. Chairman Neu thanked Dave Moody (Mutual Wholesale Drug Company) for his leadership as Chairman and his many years of service to the Association. He also briefed the Executive Committee on the day he spent with staff getting to know them and their areas of responsibility better. He assured the Executive Committee that the staff is performing at a high level and the Association is in capable hands.

B. **Antitrust Policy Review (Executive Committee Materials, Page 3).**

Richard L. Frank (OFW Law), HDMA outside counsel, reminded the Executive Committee of HDMA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no problems. Mr. Frank will monitor the conversation and, if necessary and appropriate, interrupt proceedings if topics or conversations raised concerns regarding antitrust compliance.

C. **Approval of Prior Meetings Minutes (Executive Committee Materials, Pages 4-16).**

Mr. Frank drew the Executive Committee's attention to the minutes of the September 30, 2012 Executive Committee meeting in Manalapan, Florida.

Action: On motion duly made and seconded, the minutes of the September 30, 2012 Executive Committee meeting were approved.

Mr. Frank drew the Executive Committee's attention to the minutes of the November 16, 2012 Executive Committee conference call.

Action: On motion duly made and seconded, the minutes of the November 16, 2012 Executive Committee conference call were approved.

Mr. Frank drew the Executive Committee's attention to minutes of the December 14, 2012 Executive Committee conference call.

Action: On motion duly made and seconded, the minutes of the December 14, 2012 conference call were approved.

D. Legal Issues Report.

Mr. Frank presented the legal issues update.

1. Qui Tam Litigation – There is no new activity in connection with this lawsuit. Plaintiff Streck has moved for entry of final judgment to the court's July 3, 2012 Order which dismissed the service fee defendants entirely from the case. The service fee defendants raised no objections to entering a final Order. If the court grants Plaintiff's motion, the dismissal of the service fee defendants in the case becomes appealable and this part of the case could move to briefing before the Third Circuit U.S. Court of Appeals.

2. Grant Jury Subpoena in Puerto Rico Distributor Investigation – On December 7, 2012, a federal grand jury returned a 61-count indictment against 23 individuals and three corporations for various offenses involving the wholesale distribution of prescription drugs. The indictment alleged criminal drug diversion by Martin Thuna and associates through various companies, including Drogueria de la Villa. Drogueria is a subsidiary of HDMA member FMC Distributors. HDMA has previously provided documents to the government in connection with this investigation. Mr. Frank noted that it is unlikely the government will be interested in HDMA for further documents or as a fact witness. It is also unlikely that the defense would subpoena testimony or documents from HDMA.

   In response to a question regarding membership of FMC, Mr. Frank noted that the By-Laws provide that a criminal conviction of any member may subject that member to expulsion by the Executive Committee of the Board of Directors. However, the By-Laws do not provide the same type of action for an indictment.

3. State of West Virginia Lawsuit – Former West Virginia Attorney General Darrell McGraw sued 14 out-of-state drug distributors alleging violations of the state Controlled Substances Act and Consumer Credit and Protection Act for their roles in allegedly supplying controlled substances to state "pill mills." With Mr. McGraw's recent defeat in the election of Republican opponent Patrick Morrisey, it is unclear whether or on what schedule these lawsuits will proceed. Mr. Moody reported that recently district attorneys in counties in West Virginia have brought or threatened similar lawsuits on a local basis. Staff was asked to gather additional information about these actions and circulate it to members.

4. DEA Actions in Florida – the CVS Caremark matter appears to be resolved. At the end of November 2012, DEA instituted registration revocation proceedings against three Walgreen retail stores in Florida but did not immediately suspend their registrations. These matters are still pending.

5. Arizona's Suit Against McKesson – The state sued McKesson alleging violation of the state consumer fraud law. The state alleges that McKesson provided false and misleading average wholesale price information to First Databank and Medi-Span, thereby causing false and inflated prices for the retail sale of certain drugs. This case is pending.

II. **FINANCIAL/GOVERNANCE MATTERS (Executive Committee Materials, Tab A, Pages 18-32).** Ms. Ann Bittman (HDMA Executive Vice President & COO) presented the 2012 year-end unaudited financial statements and an update on the 2013 budget.

A. **2012 Unaudited Financial Results.**

Ms. Bittman reported that HDMA ended 2012 with an unaudited operating net surplus of $282,000 versus a projected net surplus of $242,000 and an original budgeted net surplus of zero. The surplus was the result of higher manufacturer dues revenue, increased exhibit fees at DMC, additional sponsors at the ABMM, and moving the SBDA reserve fund into other income to cover law firm work on specialty matters.

Overall, operating revenue was $11.85 million, slightly under projection and significantly ahead of the original budget. Operating expenses were $11.57 million, slightly under the latest projection and 2% over the Original Budget.

The reserve fund experienced an excellent gain of $1.358 million, or 12% in 2012 due, in large part, to the performance of the overall market. Reserve fund expenditures included $62,000 for Phase 1 of the APCO public relations project with another $187,500 for that project to be spent during the first quarter of 2013. The reserve fund balance sits at $11.935 million as of year-end.

HDMA's auditors Tate & Tyron are finishing their work and will submit a draft audit report by the end of February. To date, they have noted no problems or proposed adjustments to the financial statements.

B. **2013 Budget Update.**

Slightly less than two months into the new year, dues collections are ahead of schedule. However, manufacturer dues are projected to be under budget for the year due to consolidation and resignations. Ninety-seven percent of pledged sponsorship revenue has already been received. Sponsorships for DMC and BLC are over initial budgeted projections.

C. **Organizational Goals (Executive Committee Materials, Pages 29-32).**

President Gray briefly reviewed the Association's organizational goals for 2013.

III. **MEMBERSHIP REPORT (Tab B, Pages 33-36).** Mr. Perry Fri (HDMA Senior Vice President, Industry Relations, Membership & Education) presented the Membership Report. There is one new Distributor member with three members resigned or not renewed. Total number of Distributor members sits at 33. Associate members are down from 155 to 142. Allied members have increased from 50 to 54.

IV. **PUBLIC RELATIONS RESEARCH REPORT (Tab C, Page 37 – Handout).** Mr. John Parker (HDMA Vice President, Communications) provided a brief background on Phase 1 of the public relations project and the selection of APCO to be the public relations partner. Mr. Michael Tuffin (Managing Director, Washington, DC, APCO Worldwide) introduced the work to date, which involved mostly research of opinion leaders and views of thought leaders about the problem of controlled substance diversion and abuse and the roles played by doctors, clinics, distributors, manufacturers and government. APCO conducted a series of focus groups and interviews, looking at who opinion leaders blame for drug abuse and diversion and possible solutions. Quantitative research will focus on what messages and platforms may be effective to publicize the extensive efforts made by distributors to address the problem. APCO recommended that HDMA be a primary resource in getting the story out and helping respond to crises.

Phase 2, scheduled from March to December 2013, will involve an educational program, developing messages for crisis and rapid response, creating communications tools for this program, educating target stakeholders and speaking at relevant events.

Action: On motion duly made and seconded, the Executive Committee approved Phase 2 with a $265,000 budget to be taken out of reserves. Chairman Neu reiterated his interest in having the APCO project continue in coordination with work being done by Rand.

V. **DISCUSSION ISSUES (Executive Committee Materials, Tab D).**

A. **Pedigree/Traceability (Page 41).**

Liz Gallenagh, Esq. (HDMA Vice President, Government Affairs and General Counsel) provided an update on recent federal activity regarding pedigree and traceability. Working draft bills are currently circulating in the House (Representatives Latta, Matheson, and Upton) and the Senate (Senators Burr, Bennet, Alexander, and Harkin). HDMA is part of a supply chain coalition working hard to find a compromise solution to require and implement pedigree and traceability with federal preemption. Other key players include FDA and Pew. With the California requirements becoming effective in 2015, manufacturers are anxious to see a federal solution. The coalition is targeting the summer of 2013 to consider a bill or the industry focus may shift to California. Mr. Gallenagh discussed the key issues being debated by the various parties.

B. **Sunshine Act Final Rule (Page 44).**

Mr. Patrick Kelly (HDMA Senior Vice President, Government Affairs) briefed the Executive Committee on the newly released final Sunshine Act rules which explicitly apply the reporting requirements to distributors. In an action which

appeared inconsistent with the Sunshine Act statute and the regulatory proposal, CMS's final rule requires that if the distributor holds title to the goods, they are covered by the rule and must make annual transparency reports of certain marketing expenses. The Reimbursement Task Force is considering the rule and seeking to ascertain its exact impact on HDMA members. HDMA plans to meet with CMS and to visit interested leaders on Capitol Hill. If these initial actions do not bear fruit, a lawsuit may be considered.

C. **ASP and Sequestration (Page 50).**

On March 1, 2013, the ASP reimbursement for Part B Medicare will revert to ASP plus 4%. This will be caused in part by sequestration. HDMA is attempting to maintain the exemption for prompt pay discount.

D. **Regulatory Affairs (Page 51).**

Ms. Anita Ducca (HDMA Vice President, Regulatory Affairs) provided an update on regulatory matters, including postponement for seven additional years of the DOT tote marking requirement; further engagement with DEA, including Al Santos (Deputy to Joe Rannazzisi) who will speak at the DMC and the possibility of a face-to-face meeting with DEA. USP has agreed to not move forward with its comprehensive GDP/security guidance. There is significant new activity on hydrocodone combination products with several Congressional and DEA efforts to have them rescheduled from Schedule 3 to Schedule 2. A ruling from FDA regarding the proprietary of such a rescheduling is expected soon.

Disposal of DEA products is also becoming a growing challenge for distributors. HDMA has filed a comment and is urging the establishment of an interagency task force.

VI. **UPDATED DASHBOARD (Executive Committee Materials, Tab E, Page 67).** Mr. Patrick Kelly reviewed the current issues dashboard, noting only one significant change with disposal/take-back issues being elevated from a B to an A.

VII. **CENTER FOR HEALTHCARE SUPPLY CHAIN RESEARCH.** Ms. Karen Ribler (Executive Vice President & COO, Center for Healthcare Supply Chain Research) presented the Center report. Two vacancies exist on the Center Board. The following nominations were submitted:

1. Peyton R. Howell, MHA (replaces Tony Pera). Ms. Howell is Senior Vice President of AmerisourceBergen Corporation and President, Global Sourcing and Manufacturer Relationships.

2. Kirk Kaminsky (replaces Mike Walchirk). Mr. Kaminsky is Vice President, Strategy and Business Development, McKesson Corporation.

Action: On motion duly made and seconded, the slate of nominees to fill seats on the Center Board were approved.

A discussion ensued regarding nominations for the 2013 Nexus Award. The committee members agreed with a proposal from Mr. Gray that, going forward, nominations for the Nexus Award be solicited from only the HDMA Board, the Center Board and past Nexus Award winners who are still in the industry. Further nominations will be solicited in this manner and the Executive Committee will convene by telephone conference over the next month or two to select the winner.

VIII. **MEETINGS, CONFERENCES, AND EDUCATIONAL PROGRAMS (Executive Committee Materials, Tab G).** No discussion.

IX. **EXECUTIVE SESSION.** (Separate confidential minutes.)

There being no further business, the conference call adjourned.

Prepared by:

Richard L. Frank, Counsel
Dated: March 20, 2012

Approved by:

Ann W. Bittman, HDMA Secretary
Dated: March 20, 2012

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

EXECUTIVE COMMITTEE MEETING

J.W. Marriott Orlando, Grande Lakes
Orlando, FL

June 2, 2013

Minutes of the
HDMA Executive Committee Meeting

J.W. Marriott Orlando, Grande Lakes
Orlando, FL

June 2, 2013

ATTENDEES

HDMA Executive Committee Members Present:

David Neu (Chair)	Senior Vice President and President, AmerisourceBergen Drug Corporation
Ted Scherr (Vice Chair)	President & CEO, Dakota Drug, Inc.
Ken Couch	President, Smith Drug Company
John Gray	President & CEO, HDMA
Paul Julian (by telephone)	Executive Vice President & Group President, McKesson Corp.
Mike Kaufmann	CEO, Pharmaceutical Segment, Cardinal Health, Inc.
David Moody	CEO, Mutual Wholesale Drug Company
Dale Smith	Chairman and CEO, HD Smith

HDMA and Center for Healthcare Supply Chain Research (HSCR) Staff Present:

Ann Bittman	HDMA Executive Vice President & COO
Anita Ducca	HDMA Vice President, Regulatory Affairs
Perry Fri	HDMA Senior Vice President, Industry Relations, Membership & Education
Elizabeth Gallenagh	HDMA Vice President, Government Affairs and General Counsel
Patrick Kelly	HDMA Senior Vice President, Government Affairs
Brooke Naylor	HDMA Vice President, Meetings & Conferences
John Parker	HDMA Vice President, Communications
Ted Pezzullo	HDMA Vice President, Information Technology and Facilities
Karen Ribler	Executive Vice President & COO, CHSCR

Legal Counsel:

Arthur Tsien, Esq.	Olsson Frank Weeda Terman Matz PC

Guest:

George Koch, Esq.

PROCEEDINGS

I. **WELCOME AND ADMINISTRATIVE MATTERS.** Chairman Dave Neu (AmerisourceBergen Drug Company) called the meeting to order at 11:05 am and welcomed all attendees.

A. **Antitrust Policy Review (Executive Committee Materials, Page 4).**

Arthur Tsien (OFW Law, HDMA outside counsel) reminded the Executive Committee of HDMA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no problems. He stated that he will monitor the conversation and, if necessary and appropriate, interrupt proceedings if topics or conversations raised concerns regarding antitrust compliance.

B. **Approval of Prior Meeting Minutes (Executive Committee Materials, Page 6).**

John Gray (HDMA President and CEO) drew the Executive Committee's attention to the minutes of the February 22, 2013 Executive Committee meeting in Washington, D.C.

Action: On motion duly made and seconded, the minutes of the February 22, 2013 Executive Committee meeting were approved.

C. **Legal Issues Update.**

Mr. Tsien presented the legal issues update.

1. HHS Medical Privacy Regulations – In the preamble to its final medical privacy regulations issued in January 2013, HHS adopted several very restrictive interpretations that effectively hinder "refill reminder" letters, sponsored by pharmaceutical companies, that retail pharmacies send their patients without patient authorization (affirmative patient opt-in). This issue is potentially of interest to the extent that distributor members offer network and other services to their retail pharmacy customers.

2. *Walsh v. AmerisourceBergen Corp.* – In December 2011, plaintiff Walsh, a former AmerisourceBergen internal auditor, filed a federal *qui tam* whistleblower case against AmerisourceBergen in Pennsylvania. In late 2012, the United States declined to intervene. In February 2013, the complaint was unsealed. The suit alleges that AmerisourceBergen offered free pill-counting machines and other discounts to independent pharmacies to induce them into entering into vendor relationships with AmerisourceBergen, in violation of the False Claims Act. The case is pending.

3. DEA Matters

   a. DEA Settlement with UPS. In March 2013, DEA entered into a Non-Prosecution Agreement with UPS in which UPS agreed to forfeit $40 million in payments it had received from allegedly unlawful online pharmacies. UPS also agreed to implement a compliance program designed to ensure that unlawful online pharmacies will not be able to use UPS's services to distribute drugs.

   b. *Walgreens v. DEA*. As previously summarized, DEA had issued an immediate suspension order to a Walgreens distribution facility in Florida in 2012, and Walgreens sought judicial review of the order. The case was argued before the U.S. Court of Appeals for the D.C. Circuit in March 2013, so a decision may be imminent.

   c. DEA Settlement with CVS. In April 2013, CVS agreed to pay $11 million in civil penalties to settle allegations regarding recordkeeping violations.

4. Previously Reported Matters – There were no significant developments involving other previously reported matters.

II. DISCUSSION ISSUES

A. Pedigree/Traceability Legislation (Executive Committee Materials, Page 44).

Following an introduction by Mr. Gray, Liz Gallenagh (HDMA Vice President, Government Affairs and General Counsel) provided an update on federal pedigree and traceability legislation. Among other differences, requirements in the House bill would require FDA rulemaking for "Phase 2" unit level traceability to become effective, while in the Senate bill "Phase 2" would be self-effectuating. In addition, in the Senate bill, federal requirements for licensure would be a "floor," with no "ceiling" on more stringent state requirements. Under the House bill, federal requirements would be both a "floor" and a "ceiling" on state licensure requirements. Extensive discussion followed, including HDMA's concerns with the Pharmaceutical Distribution Security Alliance (PDSA).

Action: On motion duly made and seconded, the Executive Committee recommended to the HDMA Board that: (1) HDMA continue to support federal legislation that would establish federal pedigree requirements that preempt state requirements, and (ii) HDMA continue to participate in PDSA.

Mr. Gray commended Ms. Gallenagh for her efforts on pedigree legislation.

B. **Sunshine Rule (Executive Committee Materials, Page 53).**

Patrick Kelly (HDMA Senior Vice President, Government Affairs) discussed CMS's final Sunshine Rule and HDMA's efforts to get distributors excluded from the scope of the final rule. CMS is said to be working on a "Subregulatory Guidance" that would clarify that the final rule does not apply to full service distributors. An HDMA Task Force draft letter to OMB requests, in the alternative, a 36 month extension of the Sunshine Rule's compliance date if a Guidance to address HDMA's concerns cannot be adopted. Following extensive discussion, there was general agreement that the letter to CMS should not ask for a 36 month extension.

Action: On motion duly made and seconded, the Executive Committee recommended that the Board direct that the comment to OMB not ask for a 36 month extension of the compliance date of the Sunshine Rule.

C. **ASP and Sequestration (Executive Committee Materials, Page 55).**

Mr. Kelly reported that HDMA is seeking to have the planned 2% sequestration cut in reimbursement for services and drugs limited to services, and not be applied to Part B drugs. During discussion, there was general agreement that this effort needs to proceed, even if it is unlikely to succeed.

D. **Pfizer Direct-To-Consumer Sales (Executive Committee Materials, Page 57).**

There was brief discussion regarding Pfizer's announced plans to sell prescription drugs directly to consumers. Pfizer's intent appears to be to offer an alternative to questionable Internet pharmacy sales, not to bypass distributors and retail pharmacies.

III. **UPDATE ON PUBLIC RELATIONS PROJECTS (Executive Committee Materials, Page).**

A. **APCO (Executive Committee Materials, Page 24).**

John Parker (HDMA Vice President, Communications) gave a brief overview of his planned presentation to the Board regarding the ongoing APCO project on improving public relations with regard to prescription drug diversion.

B. **Senator Boxer's Draft Legislation (Commission To Study Prescription Drug Abuse).**

Mr. Kelly discussed Senator Barbara Boxer's (D-CA) draft legislation that would establish a commission with industry and government representatives to study prescription drug abuse and issue a non-binding report. Discussion followed.

Action: On motion duly made and seconded, the Executive Committee recommended that the Board direct HDMA to support the commission concept, and to work with Senator Boxer's staff to ensure that the commission's report does not devolve into an enforcement-based recommendation to Congress.

C. **RAND Study Proposal (Executive Committee Materials, Page 37).**

Mr. Gray discussed a proposal from RAND to undertake a study entitled "Improving Prescription Drug Regulation Policy." If approved, an initial presentation regarding the project will be presented in September.

Action: On motion duly made and seconded, the Executive Committee authorized spending $500,000 from HDMA's reserve fund to fund the study.

* * *

There being no further business, on motion duly made and seconded, the meeting was adjourned at 12:40 pm.

Prepared by:

Arthur Y. Tsien, Counsel
Dated: June 26, 2013

Approved by:

Ann W. Bittman, HDMA Secretary
Dated: June 26, 2013

Minutes of the
HDMA Executive Committee Meeting

J.W. Marriott Desert Ridge
Scottsdale, Arizona

June 1, 2014

ATTENDANCE:

ATTENDEES

HDMA Executive Committee Members Present:

Dave Neu (Chair)	Sr. Vice President and President, AmerisourceBergen Drug Corp.
John Gray	HDMA President & CEO
Ken Couch	President, Smith Drug Company, Div. J.M. Smith Company
Mike Kaufmann (by conference call)	CEO, Pharmaceutical Segment, Cardinal Health, Inc.
David Moody	CEO, Mutual Wholesale Drug Company
Dale Smith	Chairman and CEO, H.D. Smith
Mark Walchirk (by conference call)	President, U.S. Pharmaceutical, McKesson Corporation

HDMA Executive Committee Members Absent:

Ted Scherr (Vice Chair)	President & CEO, Dakota Drug, Inc.

HDMA and Center for Healthcare Supply Chain Research (CHSCR) Staff Present:

Ann Bittman	Executive Vice President & COO
Anita Ducca	Vice President, Regulatory Affairs
Perry Fri	Executive Vice President, Industry Relations, Membership & Education
Liz Gallenagh, Esq.	Sr. Vice President, Government Affairs and General Counsel
Patrick Kelly	Executive Vice President, Government Affairs
John Parker	Sr. Vice President, Communications
Karen Ribler	Executive Vice President & COO, CHSCR

Legal Counsel:

Richard L. Frank, Esq.	Olsson Frank Weeda Terman Matz PC

PROCEEDINGS

I. **WELCOME AND ADMINISTRATIVE MATTERS.** Chairman Dave Neu (AmerisourceBergen Drug Corp.) called the meeting to order at 11:00 a.m., and welcomed all attendees to the Business and Leadership Conference. Mr. Neu previewed the agenda, highlighting discussions on implementation of the Drug Supply Chain Security Act (DSCSA) and drug abuse and diversion.

A. **Antitrust Policy Review (Executive Committee Materials, Page 12).** Counsel Richard L. Frank (OFW Law, HDMA outside counsel) reminded the Executive Committee of HDMA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no competitive concerns. He stated that he will monitor the meeting and, if necessary and appropriate, interrupt proceedings if topics or conversations raised concerns regarding antitrust compliance.

B. **Approval of Prior Meeting Minutes (Executive Committee Materials, Pages 6-11).** Mr. Frank drew the Executive Committee's attention to the minutes of the February 27, 2014 Executive Committee meeting in McLean, Virginia (The Ritz Carlton).

Action: On motion duly made and seconded, the minutes of the February 27, 2014 Executive Committee meeting were approved.

C. **Legal Issues Update (Executive Committee Materials, Pages 13-16).** Counsel Frank (OFW Law) presented the Legal Issues Update.

1. Implementation of DSCSA. Government Affairs staff and outside counsel are working on a variety of rulemaking initiatives to implement the DSCSA. A full report will be provided by Patrick Kelly (HDMA Executive Vice President, Government Affairs).

2. United States Pharmacopeia (USP). USP issued a draft document entitled, "Good Distribution Practices," which includes draft chapters on distribution practices, environmental controls, quality systems, and supply chain integrity and security. HDMA members have serious concerns about the USP initiative, given the lack of consistency with DSCSA requirements. Mr. Kelly reported that HDMA has sent a letter to USP's new CEO, Ronald T. Piervincenzi, Ph.D., expressing concern and asking for a meeting.

3. *U.S. ex rel. Streck v. Allergan, Inc., et al.* Discovery in the case is closing with several defendants settling and a briefing schedule and trial set for the two remaining defendants, Genzyme and Biogen Idec. OFW Law negotiated a limited document request to satisfy the subpoena; documents have been produced and Counsel Frank indicated that he did not anticipate any further demands on HDMA. Briefing is scheduled for December 2014, with a trial date set for March 16, 2015.

4. Hydrocodone rescheduling. Counsel Frank reported that the Drug Enforcement Administration (DEA), acting upon a recommendation from HHS, has proposed to "upschedule" hydrocodone combination drug products from Schedule III to Schedule II. HDMA, in close consultation with members and outside counsel, filed extensive comments on the proposed rule requesting a 12 to 24-month implementation period for meeting the heightened physical security requirements. Mr. Kelly reported that with over 500 comments filed, it was likely it would take up to a year for DEA to analyze the docket and issue a final rule.

5. Federal Trade Commission (FTC) actions against trade associations. In May 2014, the FTC Bureau of Competition posted a blog entry discussing the agency's ongoing attention to trade associations. While recognizing that trade associations undertake many useful and pro-competitive activities, FTC staff emphasized that associations and their members must not limit the ability of members to offer products and services competitively to potential customers. The FTC blog highlighted two cases finalized in December 2013 involving trade associations where codes of conduct ostensibly restrained trade. Counsel Frank reminded the Executive Committee of the importance of antitrust compliance and outlined the steps HDMA's outside counsel takes to review the agenda, all meeting materials, and the meeting conversations.

II. DISCUSSION TOPICS (Executive Committee Materials, Tab A, Pages 17-54).

A. **Drug Abuse and Diversion (Pages 19-26).** Mr. Kelly provided an overview of HDMA activity regarding drug abuse and diversion. There have been seven Congressional hearings in the past two months focusing on the issue with HDMA President, John Gray, testifying before the House Energy and Commerce Health Subcommittee. HDMA provided support for the Marino/Blackburn legislation. The Marino/Blackburn bill has been reintroduced with two Democratic co-sponsors – Representative Welch (D-VT) and Representative Chu (D-CA). Key elements, including provisions regarding corrective action plan and clear definition of terms, remain in the bill. Provisions requiring drug testing and background checks have been removed. The working group concept has been replaced with a joint report from FDA/CDC on federal efforts to address prescription drug abuse and the potential impact of these efforts on patients and supply chain entities.

Congressman Marino has requested a meeting with U.S. Attorney General Eric Holder, which is scheduled for June 9. Representatives from HDMA, NACDS, and the National Community Pharmacists Association (NCPA) will attend. A discussion ensued as to the appropriate representatives from HDMA. The matter will be further discussed with outside counsel, Linden Barber, Esq., who will be accompanying the industry groups.

At the direction of a bipartisan group of Senators, the Government Accountability Office (GAO) is in the process of finalizing a survey to assess the effectiveness of the federal government, particularly DEA, in its effort to reduce prescription drug abuse. Mr. Kelly reported that the draft survey should be quite helpful in eliciting

valuable responses from industry participants in painting a picture of the impact of DEA actions on the supply chain.

B. **LIFO Amendments (Pages 34-35).** A working group within the National Association of Wholesalers (NAW) continues to work to defeat LIFO amendments which will be harmful to wholesalers.

Action: On motion duly made and seconded, the Executive Committee agreed to approve $10,000 to support the NAW effort.

C. **Pedigree/Traceability Implementation.** This matter will be covered in the Board of Directors meeting.

D. **State Affairs.** This matter will be covered in the Board of Directors meeting.

III. **ABMM UPDATE.** This matter will be covered in the Board of Directors meeting.

IV. **FINANCIAL AND GOVERNANCE MATTERS (Executive Committee Meeting Materials, Tab C, Pages 57-66).**

A. **Center for Healthcare Supply Chain Research (CHSCR) Board of Directors (Page 58).** Ms. Karen Ribler (Executive Vice President & COO, CHSCR) reported that the CHSCR Board has recommended Mike Conley, Executive Director, USMM&MA Wholesale/Retail Channels and Pharmacy Affairs, Novartis, for a spot on the CHSCR Board.

Action: On motion duly made and seconded, Mike Conley was approved to serve on the CHSCR Board.

B. **Financial Update (Pages 59-66).** Ms. Ann Bittman (HDMA Executive Vice President & COO) presented the financial update through April 30. Operating revenue is $11.49 million and operating expenses $4.13 million with a current net surplus of $7.36 million. The projected $96,000 budget deficit has increased to $304,000 due primarily to lower sponsorships and increased expenses for lobbyists (Ohio and Maryland). Efforts are ongoing to reduce or eliminate this deficit by fiscal year end.

The reserve fund is far ahead of budgeted investment income ($771,000 versus $225,000) due to the portfolio's excellent returns.

Cash position is strong with $7.42 million in the bank. Reserves are currently set at $13.18 million which exceeds the target of one year's operating expenses ($12.52 million).

V. **EXECUTIVE COMMITTEE BUDGET BREAKOUT GROUP REPORTS (Executive Committee Meeting Materials, Tab D, Pages 67-108).** President Gray updated the Executive Committee on the process of evaluating alignment of HDMA's budget and needs for the next five years with the goal of ensuring adequate balance to avoid annual last-minute modifications. Three subcommittees were empanelled, including: (1)

Domestic Revenue and Business Development (Dave Moody, Mutual Wholesale Drug Company; Ted Scherr, Dakota Drug, Inc.; and Dave Neu); (2) Expenses (Mike Kaufmann, Cardinal Health, Inc.; and Dale Smith, H.D. Smith); and (3) International Revenue and Business Development (Ken Couch, Smith Drug Company, Div. J.M. Smith Company; and Mark Walchirk, McKesson Corporation). Each subcommittee held two conference calls and developed a list of options for consideration by the full Executive Committee. With regard to domestic revenue, some combination of dues increases and reserve draw-down were discussed. Regarding international revenue and business development, HDMA, in cooperation with the International Federation of Pharmaceutical Wholesalers (IFPW), will hold its first summit in China later this year. The Association is exploring ways of increasing cooperation with IFPW going forward. President Gray noted that the Association is considering a name change to possibly "Healthcare Distributors Association" or "Healthcare Distributors International."

With regard to expenses, the Committee and staff are looking at how staff compensation and benefits compare to association peers.

Following discussion, the Executive Committee asked President Gray and his staff to develop multiple scenarios for enhancing revenue and/or restraining cost increases to achieve budget balance for at least the next five years. Mr. Kaufmann suggested that members be surveyed on their views regarding HDMA State Legislative Affairs activities.

There being no further business, the meeting was adjourned.

Prepared by:

Richard L. Frank

Richard L. Frank, Counsel
Dated: June 27, 2014

Approved by:

Ann W. Bittman

Ann W. Bittman, HDMA Secretary
Dated: June 27, 2014

Minutes of the
HDMA Executive Committee Meeting
The Lodge at Pebble Beach
Pebble Beach, California
February 18, 2016

ATTENDANCE:

HDMA Executive Committee Members:

Ted Scherr, Chairman (by telephone)	President/CEO, Dakota Drug, Inc.
Jon Giacomin, Vice Chairman	CEO, Pharmaceutical Segment, Cardinal Health, Inc.
Kenneth Couch	Director, J M Smith Corporation
John Gray	President and CEO, HDMA
Robert Mauch	President, AmerisourceBergen Drug Corporation, AmerisourceBergen Corporation
David Moody	CEO, Mutual Wholesale Drug Company
Dale Smith	Chairman and CEO, H.D. Smith Holding Company
Mark Walchirk	President, US Pharmaceutical, McKesson Corporation

HDMA and Center for Healthcare Supply Chain Research (CHSCR) Staff:

Ann Bittman	Executive Vice President & COO
Perry Fri	Executive Vice President, Industry Relations, Membership & Education
Elizabeth Gallenagh, Esq.	Sr. Vice President, Government Affairs and General Counsel
Patrick Kelly	Executive Vice President, Government Affairs
Brooke Naylor	Senior Vice President, Meetings & Conferences
John Parker	Senior Vice President, Communications
Karen Ribler (by telephone)	Executive Vice President & COO, Center for Healthcare Supply Chain Research

Legal Counsel:

Richard L. Frank, Esq.	Olsson Frank Weeda Terman Matz PC

PROCEEDINGS:

I. **WELCOME AND ADMINISTRATIVE MATTERS**. HDMA Vice Chairman Jon Giacomin (Cardinal Health, Inc.) (chairing the meeting for Chairman Ted Scherr (Dakota Drug, Inc.) who participated by telephone), called the duly noticed meeting to order at 7:00 a.m., and welcomed all attendees to the Executive Committee meeting. President John Gray welcomed members and staff and previewed the agenda.

A. **Antitrust Policy Review (Executive Committee Meeting Materials, Page 4)**. Counsel Richard L. Frank (OFW Law, HDMA outside counsel) reminded the Executive Committee of HDMA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no competitive concerns. He stated that he will monitor the meeting and, if necessary and appropriate, interrupt

proceedings if topics or conversations raised concerns regarding antitrust compliance.

B. **Approval of Prior Meeting Minutes (Executive Committee Meeting Materials, Pages 5-10).** Counsel Frank drew the Executive Committee's attention to the minutes of the September 27, 2015 Executive Committee meeting.

Action: On motion duly made and seconded, the minutes of the September 27, 2015 Executive Committee meeting were approved.

C. **Legal Issues Update (Executive Committee Meeting Materials, Pages 11-17).** Counsel Frank provided the update on relevant legal activities since last September. These include:

1. *In re: Masters Pharmaceuticals, Inc.*, No. 15-1335 (D.C. Cir.) – The status of the *Masters* litigation as well as a discussion of the draft *amicus curiae* brief to be possibly filed on behalf of HDMA will be discussed later in the meeting, led by President Gray and HDMA General Counsel Gallenagh.

2. *U.S ex rel. Streck v. Allergan, Inc., et al.* – Counsel Frank briefed the Executive Committee on recent activities, including Astra Zeneca, Cephalon, and Biogen settling with Mr. Streck for a total of $55.5 million. Genzyme remains in the case, though settlement negotiations continue. Mr. Streck's counsel has indicated that once the case against the four "discount" defendants ends, they will appeal and seek to reinitiate the case that was dismissed in 2012 against the "improper service fees" defendants.

3. DEA Prosecution of Federal Express – DEA has accused FedEx of shipping controlled substances from illegal on-line pharmacies and seeks fines and penalties which could exceed $800 million. FedEx is vigorously defending the action.

4. West Virginia Litigation – HDMA filed an *amicus curiae* brief in the West Virginia Court of Appeals seeking to overturn the District Court's decision to deny defendant's Motion to Dismiss in an action where the West Virginia Attorney General has sued 14 out-of-state drug distributors for their roles in allegedly supplying controlled substances to "pill mills." The Court of Appeals, in a 3-2 Decision, upheld the lower court denial of the Motion to Dismiss and the case will go forward before the District Court. On February 3, 2016, Miami-Luken settled its part of the case.

   In January 2016, the West Virginia Attorney General filed suit against McKesson for "failing to identify, detect, report, and help stop the flood of suspicious drug orders."

   Counsel Frank characterized the series of DEA and state actions as efforts to improperly expand distributors' responsibilities beyond simply reporting suspicious orders to actually preventing the distribution of controlled

substances to licensed dispensers. States are bringing these actions for similar reasons but also in an effort to collect monetary damages and penalties.

Discussion ensued regarding how distributors can be viewed as part of the "solution" as opposed to being targeted as the "problem." Greater access to ARCOS data and/or legally permissible data sharing was briefly discussed. President Gray reported that HDMA will be meeting February 29, 2016, with new DEA Acting Administrator Chuck Rosenberg and Special Agent Louis Milione, Deputy Assistant Administrator for DEA's Office of Diversion Control.

II. **2016 ORGANIZATIONAL GOALS (Executive Committee Meeting Materials, Tab A).** President Gray briefly summarized the Association's goals for 2016.

III. **DISCUSSION ISSUES (Tab B).**

1. *Masters* (Potential *Amicus Curiae* Brief) – General Counsel Gallenagh drew the Executive Committee's attention to a draft *amicus curiae* (friend of the court) brief to be considered in connection with Masters' appeal of the DEA Suspension Order. At its September 27, 2015 meeting, the Executive Committee approved outside counsel preparing a draft brief which raised relevant public policy and legal issues but did not specifically support Masters or criticize DEA. The central theme of the draft brief is that DEA must follow statutory and regulatory requirements regarding the imposition of suspicious order reporting – notice-and-comment rulemaking required. The brief also seeks to place the role and capabilities of the distributor in context, noting that distributors neither prescribe, nor dispense controlled substances, and therefore are in no position to adjudicate the legitimacy of an order. Rather, distributors can and do report "suspicious orders" based upon customer order histories.

   Discussion ensued with all members of the Executive Committee generally supporting filing of the *amicus curiae* brief. Several members suggested softening the tone and including a statement that HDMA takes no position on the propriety of Masters' actions.

   Action: On motion duly made and seconded, the Executive Committee unanimously approved filing of an *amicus curiae* brief subject to final review and approval of the brief.

   Action: On motion duly made and seconded, the Executive Committee agreed to allow NACDS to join the brief so long as no objectionable substantive changes were made.

   Note: On February 10, 2016, the U.S. Court of Appeals suspended the briefing schedule in the *Masters* litigation subject to further order. This will permit additional time for HDMA to meet with DEA (February 29, 2016) and review Appellate *Masters'* brief.

2. Drug Abuse and Diversion – Mr. Patrick Kelly (HDMA Executive Vice President, Government Affairs) provided an update on drug abuse and diversion matters. S. 483 passed the Senate Judiciary Committee with Floor action likely relatively soon. Staff is working with supporters in the House.

3. DEA Acting Administrator Chuck Rosenberg and Office of Diversion Control Director Louis Milione have announced a series of meetings with supply chain representatives. Supply chain trade associations are scheduled to meet with DEA for a full day on February 29, 2016. Mr. Kelly circulated the draft agenda.

4. Tax Policy – Ms. Gallenagh provided an update on federal tax reform and LIFO repeal. She briefly discussed a ballot measure in Oregon which would impose a 2.5% tax plus $30,001 for all gross receipts in excess of $25 million. HDMA has joined a broad coalition of industry opponents in seeking to defeat the initiative.

   Discussion ensued.

   Action: On motion duly made and seconded, the Executive Committee approved a contribution of $25,000 out of reserves to the Grow Oregon Now Campaign to defeat the initiative.

5. Traceability Pilots – Ms. Gallenagh updated the Executive Committee on the status of DSCSA implementation and the traceability pilots. Mr. Perry Fri (HDMA Executive Vice President, Industry Relations, Membership & Education) discussed the type of data which would be generated from these programs and questions regarding data ownership. An Executive Committee Task Force consisting of Mr. Jon Giacomin and Mr. Dale Smith (H.D. Smith Holding Company) and Mr. Mark Walchirk (McKesson Corporation) will work with Mr. Fri to investigate the potential business opportunity for HDMA.

6. Reimbursement – Mr. Kelly provided an update on the final AMP rule. HDMA members achieved their objectives, particularly the exclusion of bona fide service fees.

7. DEA Waste Rule – Mr. Kelly provided an update on the DEA proposal to regulate pharmaceutical waste. HDMA filed significant comments raising concerns, particularly as the proposed rule would apply to reverse distributors and the challenge of dealing with unique state rules.

IV. **PAC PRESENTATION (Executive Committee Meeting Materials, Page 77-80).** Mr. Kelly provided an update on the status of the HDMA PAC.

V. **DASHBOARD REVIEW (Executive Committee Meeting Materials, Tab D).** Messrs. Kelly and Fri drew the Executive Committee's attention to the Issues Dashboard. There are only minor modifications.

VI. **CENTER FOR HEALTHCARE SUPPLY CHAIN RESEARCH (Executive Committee Meeting Materials, Tab E).** Ms. Karen Ribler (Executive Vice President & COO, Center for Healthcare Supply Chain Research) provided an update on Center

activities. The CEO Roundtable is scheduled for April 12th in New York City. Genentech CEO Ian Clark will be the speaker.

Ms. Ribler discussed the 2016 Nexus Award, including the recommendation that Mike McBride, Vice President, Upsher-Smith Laboratories, be honored.

Action: On motion duly made and seconded, the Executive Committee unanimously approved giving the Nexus Award to Mr. McBride.

Ms. Ribler reported that the Center Board has recommended Steve O'Dowd (Eisai, Inc.) be elected to the Center Board.

Action: On motion duly made and seconded, the Executive Committee unanimously approved Mr. O'Dowd becoming a member of the Center Board.

VII. **HDMA REBRANDING (Executive Committee Meeting Materials, Tab F and Handout).** Mr. John Parker (HDMA Senior Vice President, Communications) provided an update on the change in the Association's name to Healthcare Distribution Alliance. (HDA) Mr. Parker discussed the launch strategy and timing. At the June 12, 2016 Board/Membership Meeting, proposals to amend the Articles of Incorporation and By-Laws will be considered. Assuming approval, the new name will be formally announced at the BLC on June 13, 2016.

VIII. **CONFERENCES ((Executive Committee Meeting Materials, Tab G).** Mr. Fri briefly discussed the upcoming DMC and ABMM. Several members recommended that staff explore ways to reduce the length of the Executive Committee meetings when they are immediately before a Board meeting to avoid repetitive agenda items and to reduce the staff reporting at the Board meetings and make the Board meetings more interactive.

IX. **FINANCIAL/GOVERNANCE MATTERS (Executive Committee Meeting Materials, Tab H).**

A. Ms. Ann Bittman (HDMA Executive Vice President & COO) presented the unaudited financial statements. The Association ended 2015 with an operating deficit of $309,920 versus a budgeted deficit of $486,084. The improvement was largely due to the success of the IPDC in Brussels and the Traceability Seminar. Operating revenues and expenses were in line with the budget. Sponsorship revenue was 8.4% below the original budget. Payroll and benefits were 2.5% over budget due to the addition of a new State Affairs employee and upgraded another State Affairs position. Legal fees were $154,000 higher than budget due to two unbudgeted *amicus curiae* briefs and additional spending for the traceability regulation implementation. Travel and entertainment, state lobbying fees, production expenses, and speaker fees were all lower than budgeted. The reserve fund as of December 31, 2015, stood at $11.13 million, which is well above the target level of six months' operating expenses. The final audited financial statement for 2015 will be discussed by the Audit Committee on March 18, 2016, with a final report being delivered at the June 12, 2016 Board Meeting.

B. **Membership Report.** Mr. Fri reported that distributor membership remains stable at 34 with the addition of Seacoast Medical. Manufacturing and allied membership is down slightly due primarily to industry consolidation.

C. **New Executive Committee Members.** President Gray circulated a list of candidates to join the Executive Committee beginning June 1 2016, at which time the terms of Messrs. Ken Couch (J M Smith Corporation) and Dave Moody (Mutual Wholesale Drug Company) end. Discussion ensued.

Action: On motion duly made and seconded, the Executive Committee approved Ms. Maria Burns, Vice President, Burlington Drug Company, Inc., and Mr. Greg Drew, President, Value Drug Company, to join the Executive Committee.

There being no further business, the meeting was adjourned.

Prepared by:

Richard L. Frank, Counsel
Dated: March 12, 2016

Approved by:

Ann W. Bittman, HDMA Secretary
Dated: March 14, 2016

Minutes of the
HDA Executive Committee Meeting
The Lodge at Pebble Beach
Pebble Beach, CA
February 22, 2017

ATTENDANCE:

HDA Executive Committee Members Present:

Jon Giacomin (Chairman)	Chief Executive Officer, Pharmaceutical Segment, Cardinal Health, Inc.
Dale Smith (Vice Chairman)	Chairman and CEO, H.D. Smith Holding Company
Paul Dickson	President, Morris & Dickson Co., LLC
Greg Drew	President, Value Drug Company
John Gray	President and CEO, HDA
Robert Mauch	Executive Vice President & President, AmerisourceBergen Drug Corp., AmerisourceBergen Corporation
Ted Scherr	President/CEO, Dakota Drug, Inc.
Mark Walchirk (by telephone)	President, US Pharmaceutical, McKesson Corporation

HDA Staff:

Ann Bittman	Executive Vice President & COO, Secretary/Treasurer
Perry Fri	Executive Vice President, Industry Relations, Membership & Education and COO, HDA Research Foundation
Patrick Kelly	Executive Vice President, Government Affairs
Elizabeth Gallenagh	Senior Vice President, Government Affairs and General Counsel
John Parker	Senior Vice President, Communications
Brooke Naylor	Senior Vice President, Meetings and Conferences

Outside Legal Counsel:

Richard L. Frank, Esq.	Olsson Frank Weeda Terman Matz PC (OFW Law)

Guest:

Robert Schooling	Founder and President, Reservoir Communications Group

PROCEEDINGS:

I. **WELCOME AND ADMINISTRATIVE MATTERS.** Chairman Jon Giacomin (Cardinal Health, Inc.) called the duly-noticed meeting to order at 7:00 am and welcomed all attendees to the Executive Committee meeting. A special welcome went to Paul Dickson, the newest member of the Executive Committee. Chairman Giacomin and President Gray (HDA President and CEO) briefly reviewed the agenda and schedule.

A. **Approval of Prior Meeting Minutes (Executive Committee Meeting Materials, Pages 5-9).** Counsel Richard L. Frank (OFW Law, HDA outside counsel) drew the Executive Committee's attention to the minutes of the September 25, 2016 Executive Committee meeting.

Action: On motion duly made and seconded, the minutes of the September 25, 2016 Executive Committee meeting were approved.

B. **Antitrust Policy Review (Executive Committee Meeting Materials, Page 4).** Outside Counsel Frank reminded the Executive Committee of HDA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no competitive concerns. He stated that he will monitor the meeting and, if necessary and appropriate, interrupt proceedings if topics or conversations raised concerns regarding antitrust compliance.

C. **Legal Update (Executive Committee Meeting Materials, Pages 10-15).** Outside counsel Frank drew the Executive Committee's attention to the Legal Issues report and highlighted the following items:

1. In *U.S. ex rel. Streck v. Allergan, Inc., et al.*, all discount defendants have reached a settlement with the relator. Streck has appealed the District Court's 2012 Order dismissing the service fee defendants from the case. A question remains as to whether the District Court issued a final order allowing an appeal to the Third Circuit. We expect full briefing before the Third Circuit during 2017.

2. In *In re Masters Pharmaceuticals, Inc.*, the case was argued before a three-judge panel of the D.C. Circuit on January 2, 2017. Counsel for Masters presented several of the arguments from HDA's *amicus brief* during the argument. A decision is expected in mid-2017.

3. In the OptumRx matter, HDA, along with NCPA and NACDS, expressed their concerns that OptumRx would only do business with VAWD-certified wholesalers. On November 4, 2016, the Association of Independent Pharmaceutical Wholesalers (AIPW) filed a Complaint in the U.S. District Court for the District of Columbia against OptumRx, HHS, and CMS alleging that the defendants were excluding secondary wholesalers from the marketplace. AIPW recently filed an amended Complaint including a list of its members and a description of the harm.

4. Regarding *FWK Holdings, L.L.C. v. Actavis Elizabeth, LLC, et al.*, HDA has received a subpoena in this private drug price-fixing litigation seeking information about meetings attended by various generic drug manufacturing defendants. HDA has also received a notice to retain documents and records in *In re Generic Digoxin and Doxycycline Antitrust Litigation* similarly involving allegations against generic manufacturers.

5. Opioid-related litigation continues in West Virginia and has spread to McDowell County. In addition, the City of Everett, Washington has initiated a case against Purdue Pharma.

II. DISCUSSION ISSUES (Executive Committee Meeting Materials, Tab A).

A. Healthcare Policy Update (pages 19-24). Mr. Patrick Kelly (HDA Executive Vice President, Government Affairs) briefly discussed Congressional efforts under way to repeal and replace Obamacare, including the possibility of block grants to the states and potential negotiation between the federal government and drug manufacturers. There has also been some mention of permitting personal and commercial importation of drugs approved for non-U.S. markets. A discussion ensued regarding the best means of communicating to the government and public the role of distributors in the process, including the comparatively small costs contributed by the wholesale sector to healthcare.

Action: On motion duly made and seconded, the Executive Committee agreed to empanel a Task Force to facilitate the development of communication materials to explain the role and value of primary wholesale distributors in the supply chain.

B. Drug Abuse and Diversion (pages 25-54). Mr. John Parker (HDA Senior Vice President, Communications) provided an update on the highly inflammatory media environment regarding the role of wholesalers as well as the cases that have been brought in West Virginia. Mr. Robert Schooling (Reservoir Communications Group) discussed a proposal for the development and roll-out of a six-month Communications Program, explaining the role, in appropriate context, of the distributor.

Action: On motion duly made and seconded, $240,000 was approved for a six-month engagement of Reservoir Communications Group for message development and communications strategy.

C. Tax Reform (pages 55-72). Ms. Elizabeth Gallenagh, (HDA Senior Vice President, Government Affairs and General Counsel) noted that the recent election provides the best environment in years for federal tax reform. Budget reconciliation presents a potential vehicle for repeal of the Affordable Care Act as well as consideration of lower corporate rates, broader capital tax credits, and consideration of the border adjustability tax. HDA will continue to oppose LIFO repeal. Ms. Gallenagh also provided an update of a very active 2017 state legislative session.

D. Traceability Implementation (pages 73-84). Mr. Perry Fri (HDA Executive Vice President, Industry Relations, Membership & Education) discussed HDA's work on implementation of the Drug Supply Chain Security Act (DSCSA). Mr. Fri presented the HDA Saleable Returns Pilots Report. In the Report, the Traceability Pilots Work Group recommended two preferred methods for verification of saleable returns and now recommends further study of one of those methods, a verification router service. The Work Group has divided into two groups, one to develop the business and technical requirements of the router service and the other to consider structure and governance.

Action: On motion duly made and seconded, the Executive Committee approved $60,000 for KPMG LLC to assist with this project.

Mr. Fri also provided an update on the Saleable Returns Pilot Report.

III. 2017 PROJECTS (Executive Committee Meeting Materials, Tab B).

A. GTIN Database Project (pages 86-88). Mr. Fri provided an update on discussions with ValueCentric to facilitate this joint venture. The signed term sheet was reviewed regarding a revenue share model. The project will be known as the HDA Origin Project. Discussion ensued.

Action: On motion duly made and seconded, the revenue-sharing model was approved. A final contract with ValueCentric will be circulated to the Executive Committee prior to execution.

B. Pharmaceutical Cargo Security Coalition (PCSC) (pages 89-92). Mr. Fri provided follow-up on the proposal to integrate cargo security issues and experts into HDA. The Executive Committee generally agreed integrating PCSC members would be a good fit. Mr. Fri provided a revenue model which showed a modest annual net income from such an integration. HDA Bylaws would need to be revised to facilitate cargo security members becoming allied members of HDA.

Action: On motion duly made and seconded, the Executive Committee recommended that the Board adopt the proposed Bylaws amendment (included on page 93) to add cargo security interests as a separate category under allied members.

C. Specialty Pharmaceutical Distribution (pages 94-95). Mr. Fri indicated that HDA had received four proposals as a follow-up to studying the different methods of distributing specialty pharmaceuticals.

Action: On motion duly made and seconded, the Executive Committee approved awarding the contract to Deloitte Consulting at a cost of $325,000.

IV. PAC PRESENTATION (Executive Committee Materials, Tab C, Pages 96-99). Mr. Kelly provided an update on the activities of the HDA PAC.

V. ORGANIZATIONAL GOALS Executive Committee Materials, Tab D, Pages 100-106). Mr. Gray reviewed the internal staff document focusing on organizational goals for 2017.

VI. DASHBOARD REVIEW (Executive Committee Materials, Tab E, Pages 107-111). Mr. Kelly reviewed the amendments to the HDA Dashboard.

VII. HDA RESEARCH FOUNDATION (Executive Committee Materials, Tab F, Pages 112-118). Mr. Fri announced that the Ninth Annual CEO Roundtable would be held April

4, 2017, at the St. Regis Hotel in New York. Ms. Marilyn Tavenner (AHIP) will be the featured speaker. A discussion of the 2017 Nexus Award ensued.

The Executive Committee reaffirmed its previous decision to give the award to Mr. Michael McBride (Upsher-Smith Laboratories, Inc.)

VIII. **CONFERENCES (Executive Committee Materials, Tab G, Pages 116-118).** Mr. Fri discussed upcoming conferences, especially the feedback received from a recent survey on the Annual Board and Membership Meeting (ABMM).

IX. **FINANCIAL/GOVERNANCE MATTERS (Executive Committee Meeting Materials, Tab H, Pages 119-131).** Ms. Ann Bittman (HDA Executive Vice President & COO, Secretary/Treasurer) discussed the unaudited financial statements for 2016. Results exceeded budget with an operating deficit of $184,000 versus a budgeted deficit of $476,000. Operating revenues were $13.48 million, which was $234,000 over the original budget and $57,000 higher than projection. Operating expenses were $13.66 million, which were $57,000 lower than the original budget and $100,000 higher than projection. Ms. Bittman briefly described revenue and expense variances of note (see pages 120 and 121).

The reserve fund had an investment gain of $739,000 for the year versus budgeted investment income of $100,000. The balance in the reserve fund as of December 31, 2016 was $9.8 million, significantly above the target level of six months' operating expenses.

Financial forecasts for 2017 through 2020 remain on track and currently do not include any potential income from the GTIN/ValueCentric Project or the new cargo security members.

Membership Report. Mr. Fri provided an update on membership. An application has been received from Masters Pharmaceutical. Their application and Mr. Fri's in-person visit suggest compliance with the HDA Bylaws and membership guidelines.

Reserved Fund Investment Advisor. Mr. Scherr, Chairman of the Investment Advisory Committee, discussed the performance and costs of Morgan Stanley. The Investment Advisory Committee has recommended moving the funds to Fidelity.

Action: On motion duly made and seconded, the Executive Committee approved moving the reserve funds to Fidelity.

There being no further business, the Executive Committee meeting was adjourned.

Prepared by:

Richard L. Frank, Counsel
Dated: April 7, 2017

Approved by:

Ann W. Bittman, HDA Secretary
Dated: April 10, 2017

Minutes of the
HDA Executive Committee Meeting
J.W. Marriott Desert Ridge
Phoenix, Arizona
June 11, 2017

ATTENDANCE:

HDA Executive Committee Members Present:

Jon Giacomin (Chairman)	Chief Executive Officer, Pharmaceutical Segment, Cardinal Health, Inc.
Dale Smith (Vice Chairman)	Chairman and CEO, H.D. Smith Holding Company
Paul Dickson	President, Morris & Dickson Co., LLC
Greg Drew (by telephone)	President, Value Drug Company
John Gray	President and CEO, HDA
Robert Mauch	Executive Vice President & President, AmerisourceBergen Drug Corp., AmerisourceBergen Corporation
Ted Scherr	President/CEO, Dakota Drug, Inc.

HDA Executive Committee Members Absent:

Mark Walchirk	President, US Pharmaceutical, McKesson Corporation

HDA Staff:

Ann Bittman	Executive Vice President & COO, Secretary/Treasurer
Perry Fri	Executive Vice President, Industry Relations, Membership & Education and COO, HDA Research Foundation
Patrick Kelly	Executive Vice President, Government Affairs
Elizabeth Gallenagh	Senior Vice President, Government Affairs and General Counsel
John Parker	Senior Vice President, Communications

Outside Legal Counsel:

Richard L. Frank, Esq.	Olsson Frank Weeda Terman Matz PC (OFW Law)

Guests:

Clare Krusing, Director	Reservoir Communications Group
Robert Schooling, Founder and President	Reservoir Communications Group
Matt Heim, Senior Manager	Deloitte Consulting LLP
R. Terry Hisey, Principal	Deloitte Consulting LLP
Rob Jacoby, Principal	Deloitte Consulting LLP

PROCEEDINGS:

I. **WELCOME AND ADMINISTRATIVE MATTERS.** Chairman Jon Giacomin (Cardinal Health, Inc.) called the duly-noticed meeting to order at 10:00 am and welcomed all attendees to the Business Leadership Conference (BLC). Chairman Giacomin and President John Gray (HDA President and CEO) briefly reviewed the agenda and BLC schedule.

A. **Approval of Prior Meeting Minutes (Executive Committee Meeting Materials, Pages 4-9).** Outside Counsel Richard L. Frank (OFW Law,) drew the Executive Committee's attention to the minutes of the February 22, 2017 Executive Committee meeting.

Action: On motion duly made and seconded, the minutes of the February 22, 2017 Executive Committee meeting were approved.

B. **Antitrust Policy Review (Executive Committee Meeting Materials, Page 10).** Outside Counsel Frank reminded the Executive Committee of HDA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no competitive concerns. He stated that he will monitor the meeting and, if necessary and appropriate, interrupt proceedings if topics or conversations raised concerns regarding strict antitrust compliance.

C. **Legal Update (Board Meeting Materials, Pages 12-22).** Outside Counsel Frank explained that the full Legal Update would be provided to the Board. He did note that there were two significant trends dominating the legal landscape – federal and state investigations and lawsuits involving alleged generic drug price fixing and numerous state and local cases focusing on the costs associated with prescription drug abuse, particularly opioids.

II. **HDA RESEARCH FOUNDATION (Executive Committee Meeting Materials, Tab A, pages 12-13).** Mr. Perry Fri (HDA Executive Vice President, Industry Relations, Membership & Education and COO, Foundation) reported that the Foundation Nominating Committee recommended the following individuals be approved to sit on the Foundation Board:

Linda O'Neal, Vice President, Operations, CuraScript SD
Layne Martin, Vice President & General Manager, Supply Chain Solutions, McKesson Specialty Health
Jeffrey Foreman R.Ph., President, Smith Drug Company/President, Burlington Drug Company, Smith Drug Company, Div. of J.M. Smith Corporation
Hal Harrison, Executive Vice President and CEO, Mutual Wholesale Drug Company

Action: On motion duly made and seconded, the slate of Nominees was approved to serve on the Foundation Board.

III. **ADDITIONAL PARTICIPANTS AT HDA BOARD MEETINGS (Executive Committee Meeting Materials, Tab B, pages 14-15).** President Gray proposed that each Board member attending a Board meeting be permitted to bring up to two additional senior staff for the purpose of learning and listening and, where appropriate, called upon to participate. These individuals would be non-voting and would not constitute a substitute for the designated Board member. Mr. Gray noted that many of these government affairs and/or communications professionals would benefit from hearing the Board discussion and, where appropriate, could assist in providing useful information and views to the full Board.

A discussion ensued.

Action: On motion duly made and seconded, the Executive Committee recommended that the Board permit up to two additional senior staff to accompany Board members attending Board meetings where these individuals would only attend for the "Discussion Issues" portion of the meeting, be non-voting and would not be considered a substitute for the Board member.

IV. **MEMBERSHIP ISSUES (Executive Committee Meeting Materials, Tab C, pages 16-17). Following up on discussion form the February 22, 2017 HDA Executive Committee meeting,** Mr. Fri indicated that staff believed there was a need to clarify and freshen up the membership application and review process, including Bylaw provisions. Mr. Fri discussed how Article III, A.6. of the Bylaws set forth the basic requirements for membership. The Executive Committee and Board have adopted guidelines to facilitate the implementation of this section.

Discussion ensued.

The Executive Committee decided to empanel a Task Force consisting of Messrs. Giacomin, Dale Smith (H.D. Smith Holding Company), Robert Mauch (AmerisourceBergen Drug Corp., AmerisourceBergen Corporation) and Paul Dickson (Morris & Dickson Company) to consider possible changes to the Bylaws and guidelines. The Task Force will report back to the full Executive Committee at its next meeting in September.

V. **HDA ORIGIN CONTRACT FINALIZATION (Executive Committee Meeting Materials, Tab D. pages 21-24 and Handout).** Mr. Fri provided background on the need for the industry to develop a method for identifying GTIN data for purposes of compliance with the DSCSA. The HDA Executive Committee, , decided to pursue an agreement with ValueCentric to facilitate this project. The draft contract between the parties was circulated to the Executive Committee for review. It is a 10-year agreement with the opportunity for a 5-year renewal. HDA would own the data; ValueCentric would own the technology and process. There would be no direct HDA financial investment. The contract spells out the revenue share, audit rights and calls for an Oversight Committee. A beta test is currently ongoing. Mr. Fri indicated that GDSN was considered too complex to help industry meet the FDA deadlines. However, ultimately, a goal could be for the Origin project to be GDSN compliant.

A discussion ensued.

Action: On motion duly made and seconded, the principles set forth in the June 9, 2017 draft contract were approved.

Mr. Mauch suggested that HDA identify staff responsibilities along with those that would be given to ValueCentric. He also suggested the staff consider whether it has sufficient resources to meet this new obligation.

VI. **SPECIALTY PHARMACEUTICAL DISTRIBUTION STUDY (Executive Committee Meeting Materials, Tab E, pages 25-46).** Mr. Fri drew the Executive Committee's attention to the Specialty Distribution Channel Analysis prepared by Deloitte (draft version). The study is designed to assess the landscape and changes taking place in the specialty pharmaceutical industry and the distribution of these products. The principal focus is on how decision making is made by specialty pharmaceutical manufacturers in selecting the best means to get to market. The study also focused generally on means of enhancing services offered by individual distributors.

Representatives from Deloitte, including Mr. Jacoby, Mr. Hisey, and Mr. Heim, presented the top line findings and responded to member inquiries.

Following discussion, the Executive Committee decided to individually further review the study findings and include the item on the agenda for the September meeting to decide on appropriate next steps.

VII. **PUBLIC RELATIONS CAMPAIGN AND INDUSTRY VALUE PROPOSITION (Executive Committee Materials, Tab F, pages 47-54 and Handout).** Mr. John Parker (HDA Senior Vice President, Communications) outlined the challenges faced by the pharmaceutical distribution industry with particular focus on prescription drug abuse. Challenges include activities at the federal, state and local levels and a significant amount of press attention. The Executive Committee had concluded that distributors needed to better articulate their role in the supply chain and the efforts currently be undertaken to curtail prescription drug diversion and abuse.

Mr. Parker introduced Mr. Robert Schooling and Ms. Clare Krusing from Reservoir Communications Group who presented the results of their initial study into the best means of communicating the role of the prescription drug distributor in addressing prescription drug abuse.

Discussion ensued.

The Executive Committee generally supported recommendations 2 through 5 but noted additional time and clarification would be needed with respect to recommendation 1. The committee requested that Reservoir come back with a more specific document, including strategic options, as soon as possible.

There being no further business, the Executive Committee meeting was adjourned.

Prepared by:

Richard L. Frank, Counsel
Dated: July 14, 2017

Approved by:

Ann W. Bittman, HDA Secretary
Dated: July 17, 2017